510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041878

B. Purpose for Submission:
Modification to existing device Dade Behring, Inc., N Latex Cystatin C (k003503)

C. Analyte:
Cystatin C

D. Type of Test:
Quantitative Particle-enhanced immunonephelometry

E. Applicant:
DADE BEHRING, INC.

F. Proprietary and Established Names:
N LATEX CYSTATIN C

G. Regulatory Information:

1. Regulation section:
   21CFR §862.1225 -Creatinine test system.
2. Classification:
   Class 2
3. Product Code:
   NDY
4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended/Indication(s) for use:
   N Latex Cystatin C is an in vitro diagnostics kit containing reagents for the quantitative determination of cystatin C in human serum and heparinized plasma by means of particle-enhanced immunonephelometry using BN™ Systems. Cystatin C measurements are used in the diagnosis and treatment of renal diseases.

2. Special condition for use statement(s):
   This product is for prescription use only.

3. Special instrument Requirements:
   BN™ Systems

I. Device Description:

The N Latex Cystatin C assay kit consists of a suspension of polystyrene particles coated with specific antibodies to human cystatin C, rabbit immunoglobulin in a buffered solution, an aqueous solution of polyethylene glycol sorbitan monolaureate and polyethylene glycol ether, and two lyophilized control materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   N Latex Cystatin C

2. Predicate K number(s):
   k003503

3. Comparison with predicate
   The two products have the same intended use, operating principle and reagent composition.

Similarities		
Item	**Device**	**Predicate**
Intended Use	N Latex Cystatin C is an *in vitro* diagnostics kit containing reagents for the quantitative determination of cystatin C in human serum and heparinized plasma by means of particle-enhanced immunonephelometry using the BN™ Systems. Cystatin C measurements are used in the diagnosis and treatment of renal diseases.	N Latex Cystatin C is an *in vitro* diagnostics kit containing reagents for the quantitative determination of cystatin C in human serum and heparinized plasma by means of particle-enhanced immunonephelometry using BN™ Systems. Cystatin C measurements are used in the diagnosis and treatment of renal diseases.
Principle	Polystyrene particles coated with specific antibodies to human cystatin C are aggregated when mixed with samples containing human cystatin C. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.	Polystyrene particles coated with specific antibodies to human cystatin C are aggregated when mixed with samples containing human cystatin C. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.
Sample Type	Serum or heparinized plasma	Serum or heparinized plasma
Instrumentation	Nephelometry (BN™ Systems)	Nephelometry (BN™ Systems)

Differences		
Item	**Device**	**Predicate**
5. Kit Components	N Cystatin C Reagent - liquid N Cystatin C Supplementary Reagent A - liquid N Cystatin C Supplementary Reagent B - liquid N Cystatin C Control Level 1 - lyophilized N Cystatin C Control Level 2 - lyophilized	N Cystatin C Reagent - lyophilized N Cystatin C Supplementary Reagent A - liquid N Cystatin C Supplementary Reagent B - liquid N Cystatin C Control - lyophilized

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Polystyrene particles coated with specific antibodies to human cystatin C are aggregated when mixed with samples containing human cystatin C. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the relevant protein in the sample. The result is evaluated by comparison with a standard of known concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The N Latex Cystatin C assay was used to measure cystatin C concentrations in N Cystatin C Control Level 1 and 2, three serum pools and three plasma pools ranging from 0.8 to 7.1 mg/ L. Duplicate determinations from two runs over twenty days were performed using a BN™ System
Within run % C.V. ranged from 1.5 to 3.1
Between run % C.V. ranged from 1.5 to 3.5
Total % C.V. ranged from 2.4 to 4.3

b. Linearity/assay reportable range:

A sample with high concentration of analyte was serially diluted down to the lower measuring range (approximately 10% dilution steps). Each dilution was tested in replicates of five, and the mean % recovery was determined (% Recovery = mean - measured concentration x 100 / theoretical concentration). In addition, the linear regression [x-axis: theoretical concentration vs. y-axis: measured concentration] was calculated for the analyte. The acceptance criterion was established as the % recovery between 80 and 120 %, with a slope between 0.9 and 1.1 and correlation coefficient of ≥0.95.

c. Traceability (controls, calibrators, or method):

Not Applicable - subject of k003503

d. Detection limit:
Analytical sensitivity is defined as the minimal detectable level of analyte, which can be determined. This value was calculated as the mean signal of twenty replicates of N-Diluent + 2.0 SD – intercept/slope. The analytical sensitivity acceptance criterion was established as the calculated sensitivity must be less than the lowest calibrator value and was determined to be 0.05 mg/L.

e. Analytical specificity:
No interference was observed with immunosuppressive drugs (Cyclosporine, Tacrolimus, Sirolimus, Mycophenolate or Azathioprine). Interference from monoclonal or polyclonal antibodies used in the treatment of transplant patiens has not been evaluated.

f. Assay cut-off:
Not Applicable - subject of k003503

2. Comparison studies:
   a. Method comparison with predicate device:
   The current N Latex Cystatin C assay (lyophilized) was compared to the modified N Latex Cystatin C assay (liquid) by evaluating 70 serum samples ranging from 0.56 to 7.5 mg/L.

Method Comparison Study

Assay	(n=)	Slope	Intercept	Correlation Coefficient
N Latex Cystatin C	70	0.99	-0.002	0.999

   b. Matrix comparison:
   Not applicable - subject of k003503
3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable - subject of k003503
   b. Clinical specificity:
   Not Applicable - subject of k003503
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not Applicable - subject of k003503
5. Expected values/Reference range:
   Not Applicable - subject of k003503

N. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.